

CLAIMS:

1. A method of detecting a clonal population of cells in a biological sample, which clonal cells are characterised by a diagnostically distinctive nucleic acid region, said method comprising co-localising the subject nucleic acid regions derived from said sample, which co-localisation is based on nucleotide sequence identity, and qualitatively and/or quantitatively detecting the levels of said co-localised nucleic acid regions wherein a higher level of a co-localised nucleic acid region population relative to background levels is indicative of the presence of a clonal population of cells in said sample.
2. A method for diagnosing and/or monitoring a clonal population of cells in a mammal, which clonal cells are characterised by a diagnostically distinctive nucleic acid region, said method comprising co-localising the subject nucleic acid regions derived from a biological sample derived from said mammal, which co-localisation is based on nucleotide sequence identity, and qualitatively and/or quantitatively detecting the levels of said co-localised nucleic acid regions wherein a higher level of a co-localised nucleic acid region population relative to background levels is indicative of the presence of a clonal population of cells in said sample.
3. The method according to claim 1 or 2 wherein said clonal population of cells is a neoplastic clonal population.
4. The method according to claim 3 wherein said neoplastic population of cells corresponds to a leukaemia, lymphoma or myeloma.
5. The method according to claim 4 wherein said leukaemia is acute myeloid leukaemia or acute lymphoblastic leukaemia.
6. The method according to claim 1 or 2 wherein said clonal population of cells is a non-neoplastic clonal population of cells.

7. The method according to claim 6 wherein said non-neoplastic population of cells corresponds to a myelodysplasia, polycythaemia vera or a myeloproliferative syndrome.
8. The method according to claim 3 or 6 wherein said clonal population of cells is a clonal immune cell population.
9. The method according to claim 8 wherein said immune cell is a T cell or a B cell.
10. The method according to claim 1 or 2 wherein said clonal population of cells is a clonal microorganism population.
11. The method according to any one of claims 1-10 wherein said nucleic acid region is a DNA region.
12. The method according to claim 11 wherein said diagnostically distinctive DNA region is mitochondrial DNA or a microsatellite.
13. The method according to claim 12, wherein said mitochondrial DNA is mitochondrial D loop DNA.
14. The method according to claim 5 wherein said nucleic acid region is a DNA region and said diagnostically distinctive DNA region is mitochondrial D loop DNA.
15. The method according to any one of claims 1-14 wherein said co-localisation is achieved utilising any one of the techniques of:
 - (i) Denaturing gradient electrophoresis.
 - (ii) Temperature gradient denaturing electrophoresis
 - (iii) Constant denaturing electrophoresis

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- (iv) Single strand conformational electrophoresis
 - (v) Denaturing high performance liquid chromatography
 - (vi) Microassays
 - (vii) Mass spectrometry
16. The method according to claim 14 wherein said co-localisation is achieved utilising denaturing gel or capillary electrophoresis.
17. A method for diagnosing and/or monitoring a mammalian disease condition characterised by the presence of a clonal population of cells, which clonal cells are characterised by a diagnostically distinctive nucleic acid region, said method comprising co-localising the subject nucleic acid regions derived from a biological sample derived from said mammal, which co-localisation is based on nucleotide sequence identity and qualitatively and/or quantitatively detecting the levels of said co-localised nucleic acid regions wherein a higher level of the co-localised nucleic acid region population relative to background levels is indicative of the presence of a clonal population of cells in said sample.
18. The method according to claim 17 wherein said clonal population of cells is a neoplastic clonal population.
19. The method according to claim 18 wherein said disease condition is leukaemia, lymphoma or myeloma.
20. The method according to claim 19 wherein said leukaemia is acute myeloid leukaemia or acute lymphoblastic leukaemia.
21. The method according to claim 17 wherein said clonal population of cells is a non-neoplastic clonal population of cells.

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22. The method according to claim 21 wherein said disease condition is myelodysplasia, polycythaemia vera or a myeloproliferative syndrome.
23. The method according to claim 18 or 21 wherein said clonal population of cells is a clonal immune cell population.
24. The method according to claim 23 wherein said immune cell is a T cell or a B cell.
25. The method according to claim 17 wherein said clonal population of cells is a clonal microorganism population.
26. The method according to any one of claims 17-25 wherein said nucleic acid region is a DNA region.
27. The method according to claim 26 wherein said diagnostically distinctive DNA region is mitochondrial DNA or a microsatellite.
28. The method according to claim 27, wherein said mitochondrial DNA is mitochondrial D loop DNA.
29. The method according to claim 20 wherein said nucleic acid region is a DNA region and said diagnostically distinctive DNA region is mitochondrial D loop DNA.
30. The method according to any one of claims 17-29 wherein said co-localisation is achieved utilising any one of the techniques of:
 - (i) Denaturing gradient electrophoresis.
 - (ii) Temperature gradient denaturing electrophoresis
 - (iii) Constant denaturing electrophoresis
 - (iv) Single strand conformational electrophoresis

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- (v) Denaturing high performance liquid chromatography
 - (vi) Microassays
 - (vii) Mass spectrometry
31. The method according to claim 30 wherein said co-localisation is achieved utilising denaturing gel or capillary electrophoresis.